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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service D1285B

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, Florida 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-33

March 25, 1997

Joseph C. DuRant, President/CEO
Innovative Health Services, Inc.
562 Wylie Road, Suite #14
Marietta, Georgia 30067

Dear Mr. DuRant:

Inspection of your medical gas filling operation located at 6741 Sunrise Boulevard, Plantation, Florida, on March 5-10, 1997, by FDA investigators Alfred L. Chester and Clara E. Santiago, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigators documented significant deviations from the Good Manufacturing Practice (GMP) Regulations [Title 21, Code of Federal Regulations, Parts 210 and 211 (21 CFR 210 and 211)] in conjunction with the testing and release for distribution of compressed medical oxygen causing the products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act. A copy of the Inspectional Observations (FDA Form 483) issued to your unit manager, Russell H. Barron, at the conclusion of the inspection is enclosed.

Inspection revealed there is no assurance that your medical oxygen products meet applicable standards of identity, strength, quality, and purity in that you have failed to properly test at least one filled cylinder per manifold filling sequence to determine conformance with appropriate specifications prior to release for distribution. The investigators documented that calibration of the [redacted] oxygen analyzer, used by your firm for purity and identity testing, is not consistently performed in accordance with the manufacturer's directions (i.e. daily or more often, using the specified calibration gases). From January 9, 1997 to January 23, 1997, your firm did not have a high purity nitrogen standard available which is required to calibrate the "zero" on the analyzer. Failure to properly calibrate your oxygen analyzer makes any determination of purity unreliable.

The inspection also revealed that established written procedures for production and process controls designed to assure that your medical oxygen products have the identity, strength, quality, and purity they are represented to possess are not being followed; for example, calibration and maintenance of equipment, completion of batch records, assignment of lot numbers, labeling, distribution, and supervisory review. Written procedures are not established for handling complaints.

Batch production and control records are incomplete, inaccurate, and fail to document that each significant step in the manufacturing operation was completed, such as all required post fill cylinder inspections and testing. The investigators documented inaccurate label reconciliation data, invalid lot numbers, and missing information on batch production records which were reviewed and approved by a supervisor. There is no assurance that personnel have been adequately trained to provide appropriate review of batch production and control records.

Other Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. Additionally, pending applications for Agency approval (NDA, ANDA, SNDA, etc.) or export approval requests may not be approved.

In order to facilitate the Food and Drug Administration (FDA) in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other Federal agencies concerning the award of government contracts, and to resume review of any pending applications, we request that you notify this office when corrective actions are completed and you believe your facility is in compliance with the GMP regulations so that a verification inspection can be scheduled.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. As president, it is your responsibility to ensure that all medical gas products you repack and distribute are in compliance with the Act and the requirements of the GMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction,
without further notice.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, extension 263.

Sincerely,

Douglas D. Tolen
Director, Florida District

Enclosure